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QUALITY FOR LIFE

SEP 16 2011

K111278

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1. Submitter's Name.:	OTTO BOCK Health Care, LP
2. Address:	Two Carlson Parkway North, Suite 100 Minneapolis, Minnesota USA 55447-4467
3. Telephone:	763-253-5610
4. Contact Person:	William Kabitz, Quality Assurance Manager
5. Date Prepared:	May 1st, 2011
6. Registration Number:	2182293

B. Device

1. Name:	z10 Push and Brake Assist
2. Trade Name:	z10 Push and Brake Assist
3 .Common Name:	Powered Wheelchair Mover
4. Classification Name:	Wheelchair, Powered
5. Product Code:	ITI
6. Class:	II
7. Regulation Number:	21 CFR 890.3860

C. Identification of Legally Marketed Predicate Device

1. Name:	Dane Technologies Wheelchair Mover
2. Manufacture:	Dane Technologies
3. K Number:	K073701
4. Date Cleared:	January 8, 2008

D. Description of the Device

The z10 is a powerful push and brake assist for manual wheelchairs. It can also be converted into the z10-ce add-on drive with tiller control quickly and easily. In this product version, the user drives and controls the wheelchair independently.

E. Features

The special features of the z10 push and brake assist for wheelchairs includes:

- Very good operating performance, including uneven surfaces, thanks to the motor unit, suspension, and generous ground clearance of 8 cm.
- Optimum traction, even when going uphill or downhill, thanks to the rear-mounted drive.
- Range of up to 25 km* for pushing and driving, no creeping loss of battery capacity thanks to the latest Lithium-Ion battery technology.
- Speed control up to 6 km/h in 5 levels at the push of a button.
- Hills and slopes up to 20% and obstacle clearance up to 5 cm possible.
- Excellent maneuverability, including indoors.
- Very quiet operation due to the worm gear motor.

F. Intended Use Statement

In combination with a manual wheelchair, the z10 power add-on drive is intended exclusively as a push and brake assist for the transportation by an assistant of persons who are unable to walk or who have walking disabilities.

In combination with a manual wheelchair, the z10-ce power add-on drive is intended exclusively as a power add-on drive with tiller control for individual use by persons who are unable to walk or who have a walking disability, in order to transport themselves.

The wheelchair/z10 combination may only be used with the components/options listed in the instructions for use.

The z10 power add-on drive may only be used by persons who have received training. Training in use is a prerequisite in order to protect persons from danger and to operate the wheelchair/z10 combination safely and without mistakes.

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G. Technological Characteristics Summary

	z10	z10-ce
General		
Housing Metal:	Anthracite metallic	
Drive wheel	10", airless, grey	
Steering caster	N/A	8" dual, airless, grey
Anti-tipper	Swinging anti-tipper	
Driving Data		
Speed	Max. 6 km/h, 5 levels, continuous fine adjustment within each speed level	
Range	25 km according to ISO 7176-4	
Max. climbing ability	Up to 20%	
Maximum obstacle height	6 cm	4 cm
Turning radius	Depending on the radius of the manual wheelchair	
Weights		
Drive unit (without battery)	21 kg	
Tiller control with control panel	1.5 kg	
Battery pack	3.8 kg	
Wheelchair adapter plate	1.0 kg	
z10-ce steering caster unit with adapter	N/A	8.0 kg
Total weight, z10 without adapter plate	26.3 kg	34.3 kg
Maximum load capacity (including wheelchair)	160 kg	
Minimum load capacity	20 kg	
Dimensions (W x H x D)		
Drive unit including battery	335 x 580 x 450 mm	
Tiller control with control panel	550 x 520 x 180 mm	
Wheelchair with z10	Depends on the manual wheelchair, z10 does not change dimensions	
Electrical Installation		
Lithium-ion battery	24V / 18.4 Ah	
Charging time (battery drained)	Approx. 4 h	
Battery lifespan (complete charging cycles)	700 cycles (subsequently 80% charging capacity)	
Control unit	enAble 40	
Operating voltage	24 V DC	
Motor power	100 W	
Self-contacting	Yes	
Light module	(front) Optional: Hella HL 2000	
Wheelchair Adaptation		
Minimum seat height	38 cm	
Minimum seat width	38 cm	
Adaptation system	Attachment bolt with locking pin	
Compatible Otto Bock wheelchairs	Start M1/M2/M3/M4/M5, Motus, Avantgarde T/VR, Centro A3	
Compatible third-party wheelchairs	Adaptable to most wheelchair models commonly available on the market, limitations depending on the product design of the wheelchair, please request a list from Otto Bock	
Charger		
Type	Mentzer	
Mains plug	Euro-plug, 2-pin	
Power requirements	110 V	
Mains frequency	50/60 Hz	
Dimensions (W x H x D)	170 x 140 x 85 mm	
Weight	1.3 kg	

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H. Safety Testing

The safety of the z10 Push and Brake Assist has been confirmed by CE certification, and was tested by Mikes Testing Partners in Strasskarchen Germany and TÜV SÜD Product Services GmbH, Hanover, Germany to the following standards:

ISO 7176-14:2008

ISO 7176-21:2009

ANSI/RESNA WC/Vol. 2 :1998

ISO 10993-1:2003 Cytotoxicity

ISO 9999:2007 Assistive products for persons with disability

Refer to Appendic C for test reports.

Signatures:

Quality Assurance Manager_____

President & CEO US Healthcare 

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 16 2011

Otto Bock Healthcare, LP
% Mr. William Kabitz
Quality Assurance Manager
Two Carlson Parkway North, Suite 100
Minneapolis, Minnesota 55447-4467

Re: K111278
Trade/Device Name: z10 and z10ce Push and Brake Assist
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: August 30, 2011
Received: September 02, 2011

Dear Mr. Kabitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Peter Rumm, Dep Lin Div

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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APPENDIX J

Indications For Use Form

510(k) Number (if known): To be determined

Device Name: z10 and z10ce Push and Brake Assist

Indications for Use:

Provide mobility to persons physically challenged and limited to sitting positions due to:

- Palsies/Paralyses
- Loss of limbs
- Defective and/or deformed limbs
- Joint contractures
- Joint defects
- Other diseases

Prescription Use ____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111278